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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 2

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Application Number		
Filing Date		
First Named Inventor	Herman F. Staats	₩
Group Art Unit	1647	0
Examiner Name	R. Landsman	
Attorney Docket Number	180/102/2	Si

				U.S. PATENT DOC	UMENTS	986 O
Examiner Initials*	Cite No.1	U.S. Patent I	Cocument Kind Code ² (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
BL	A1	4,935,343		Allison et al.	06/19/1990	
	A2	5,008,374		Nakai et al.	04/16/1991	
	A3	5,266,311		Cerrati et al.	11/30/1993	
	A4	5,334,379		Pillai et al.	08/02/1994	
	A5	5,342,614		Nakai et al.	08/30/1994	
	A6	5,342,615		Nakai et al.	08/30/1994	
	A7	5,371,204		Nakai et al.	12/06/1994	
	A8	5,437,988		Bellini et al.	08/01/1995	
	A9	5,474,899		Lisi	12/12/1995	
	A10	5,543,140		Nakai et al.	08/06/1996	·
		5,702,698		Nakai et al.	12/30/1997	
	A12	5,728,571		Velati Bellini et al.	03/17/1998	
	A13	5,210,072		Chedid et al.	05/11/1993	
V	A14	5,206,014		Nencioni et al.	04/27/1993	
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ac		B1	WO	88/06843		Cerreti et al.	09/22/1988		
		B2	WO	91/01143		Pillai et al.	02/07/1991		
\Box		B3	wo	91/13986		Maliszewsk	09/19/1991		
		B4	wo	92/03574		Andrews et al.	03/05/1992		
		B5	wo	94/00491		Bartfai et al.	01/06/1994		
H		B6	NL	93/01929		Billiau	10/17/1994		
		B7	EP	810285		Dorssers et al.	12/03/1997		
	_	B8	EP	761688		Landon	03/12/1997		
\Box		B9	wo	96/07673		Larsen et al.	03/14/1996		
T		B10	EP	353516		Velati Bellini et al.	09/14/1994		

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¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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al	B11	JР	05-244990		Muraguchi et al.	09/23/1993		igspace
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Substitute for form 1449B/PTO	Application Number		
INFORMATION DISCLOSURE	Filing Date		
STATEMENT BY APPLICANT	First Named Inventor	Herman F. Staats	<u>"</u> -4
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(use as many sheets as necessary)	Examiner Name	R. Landsman	
Sheet 1 of 2	Attorney Docket Number	180/102/2	

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
pl	C1_	SARKAR, "Drug Metabolism in the Nasal Mucosa," Pharm. Res., p. 1-9, (1992).	X
	C2	PONTIROLI ET AL., "Nasal Administration of Glucagon and Human Calcitonin to Healthy Subjects: A Comparison of Powders and Spray Solutions and of Different Enhancing Agents," European Journal of Clinical Pharmacology, p. 427-430, (1989).	X
		ELSON ET AL., "Mucosal Adjuvants," Handbook of Mucosal Immunology, Academic Press, Inc. (San Diego), p. 391-402, (1994).	X
		REISS, T. AND STRAUSS, E., "Vaccines-Patenting Dynamics of a Powerful Healthcare Tool," Exp. Opin. Ther. Patents, Vol. 8 (No. 8), p. 951-958, (1998).	x
	C5	ELSON, "Cholera Toxin as a Mucosal Adjuvant," Mucosal Vaccines, Academic Press (New York), p. 59-72, (1996).	X
	C6_	JENKINS, "Mucosal Vaccine Delivery," Exp. Opin. Ther. Patents, p. 255-262, (1999).	X
	C7	LILLARD ET AL., "Lymphotactin Acts as an Innate Mucosal Adjuvant," J. Immuno., Vol. 162 (No. 4), p. 1959-1965, (1999).	X
	C8	MRSNY, "Adjuvants and Delivery Issues Related to Immunization: A Survey of the Recent Patent Literature," J. of Drug Targeting, Vol. 6 (No. 4), p. 243-249, (1998).	X
	C9	GIANNARINI ET AL, "Decrease of Allergen-specific T-cell Response Induced by Local Nasal Immunotherapy", Vol. 28, Clinical and Experimental Allergy, pp. 404-412 (1998).	
	C10	POCKLEY ET AL., "In Vivo Adjuvant Effect of Interleukins 5 and 6 on Rat Tear IgA Antibody Responses", Vol. 73, Immunology, pp. 19-23 (1991).	
4	C11	O'HAGAN, "Recent Advances in Vaccine Adjuvants for Systemic and Mucosal Administration", Vol. 49, J. Pharm Pharmacol, pp. 1-10 (1997).	

Examiner Signature Considered S/19(03)	۶۶	Date Considered	

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Substitute for form 1449B/PTO		Complet if Known			
		Application Number			
INF	ORMATION DIS	SCLOSURE	Filing Date		ಂ
STATEMENT BY APPLICANT			First Named Inventor	Herman F. Staats	
			Group Art Unit	1647	S
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		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
BL	C12	KRAMER ET AL., "Cytokine Mediated Effects in Mucosal Immunity", Vol. 73, Immunology and Cell Biology, pp. 389-396 (1995).	
	C13	NASH ET AL., "Recombinant Cytokines as Immunological Adjuvants", Vol. 71, Immunology and Cell Biology, pp. 367-379 (1993).	
		LIN ET AL., "Present Status of the Use of Cytokines as Adjuvants with Vaccines to Protect Against Infectious Diseases", Vol. 21, Clinical Infectious Diseases, pp. 1439-49 (1995).	
	C15	LI ET AL., "Nasal Tolerance to Experimental Autoimmune Myasthenia Gravis: Tolerance Reversal by Nasal Administration of Minute Amounts of Interferon-", Vol. 87 Clinical Immunology and Immunopathology, pp. 15-22 (1998).	
	C16	MARINARO ET AL., "Oral but Not Parenteral Interleukin (IL)-12 Redirects T Helper 2 (Th2)-type Responses to an Oral Vaccine Without Altering Mucosal IgA Responses", Vol. 185, No. 3, J Exp. Med., pp. 415-427 (February 3, 1997).	
		XIAO ET AL., "Suppression of Acute and Protracted-relapsing Experimental Allergic Encephalomyelitis by Nasal Administration of Low-dose IL-10 in Rats", Vol. 84, Journal of Neuroimmunology, pp. 230-237 (April 15, 1998) (Abstract).	
	C18	FUJIMARA ET AL., "Effect of Thromboxane A2 Antagonists on Bronchial Hyperresponsiveness Induced Immediately after Interleukin-8 Inhalation in Guinea-pigs", Vol. 122, British Journal of Pharmacology, pp. 1015-1020 (1997).	
	C19	CALLARD ET AL., "The Cytokine Facts Book", Academic Press, Harcourt and Co., Publishers, pp. 241 (1994).	
	C20	ABRAHAM ET AL., "Intranasal Immunization with Liposomes Containing IL-2 Enhances Bacterial Polysaccharide Antigen-Specific Pulmonary Secretory Antibody Response", Journal of Immunology, Vol. 149, No. 11, pp. 3719-3726 (1992).	
4		GAO ET AL., "BHV-1 Glycoprotein 1 and Recombinant Interleukin 1B Efficiently Elicit	
	C20	ABRAHAM ET AL., "Intranasal Immunization with Liposomes Containing IL-2 Enhances Bacterial Polysaccharide Antigen-Specific Pulmonary Secretory Antibody Response", Journal of Immunology, Vol. 149, No. 11, pp. 3719-3726 (1992).	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	09/874.103	오
	06/05/2001	
First Named Inventor	Herman F. Staats	
Art Unit	1647	<u> </u>
Examiner Name		
Attorney Docket Number	180/102/2	=

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¹ Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.